

§ 107.200

Nutrients	Unit of measurement	Minimum level	Maximum level
Copper	Micrograms	60
Iodine	do	5	75
Sodium	Milligrams	20	60
Potassium	do	80	200
Chloride	do	55	150

¹ The generic term "niacin" includes niacin (nicotinic acid) and niacinamide (nicotinamide).

² Required only for non-milk-based infant formulas.

In addition to the specifications established in the table in this paragraph for vitamins and minerals, the following also apply:

(b) Vitamin E shall be present at a level of at least 0.7 International Unit of vitamin E per gram of linoleic acid.

(c) Any vitamin K added shall be in the form of phyloquinone.

(d) Vitamin B₆ shall be present at a level of at least 15 micrograms of vitamin B₆ for each gram of protein in excess of 1.8 grams of protein per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container.

(e) The ratio of calcium to phosphorus in infant formula in the form prepared for consumption as directed on the container shall be no less than 1.1 and not more than 2.0.

(f) Protein shall be present in an amount not to exceed 4.5 grams per 100 kilocalories regardless of quality, and not less than 1.8 grams per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container when its biological quality is equivalent to or better than that of casein. If the biological quality of the protein is less than that of casein, the minimum amount of protein shall be increased proportionately to compensate for its lower biological quality. For example, an infant formula containing protein with a biological quality of 75 percent of casein shall contain at least 2.4 grams of protein (1.8/0.75). No protein with a biological quality less than 70 percent of casein shall be used.

[50 FR 45108, Oct. 30, 1985]

Subpart E—Infant Formula Recalls

SOURCE: 54 FR 4008, Jan. 27, 1989, unless otherwise noted.

21 CFR Ch. I (4–1–14 Edition)

§ 107.200 Food and Drug Administration-required recall.

When the Food and Drug Administration determines that an adulterated or misbranded infant formula presents a risk to human health, a manufacturer shall immediately take all actions necessary to recall that formula, extending to and including the retail level, consistent with the requirements of this subpart.

§ 107.210 Firm-initiated product removals.

(a) If a manufacturer has determined to recall voluntarily from the market an infant formula that is not subject to § 107.200 but that otherwise violates the laws and regulations administered by the Food and Drug Administration (FDA) and that would be subject to legal action, the manufacturer, upon prompt notification to FDA, shall administer such voluntary recall consistent with the requirements of this subpart.

(b) If a manufacturer has determined to withdraw voluntarily from the market an infant formula that is adulterated or misbranded in only a minor way and that would not be subject to legal action, such removal from the market is deemed to be a market withdrawal, as defined in § 7.3(j) of this chapter. As required by § 107.240(a), the manufacturer shall promptly notify FDA of such violative formula and may, but is not required to, conduct such market withdrawal consistent with the requirements of this subpart pertaining to product recalls.

§ 107.220 Scope and effect of infant formula recalls.

(a) The requirements of this subpart apply:

(1) When the Food and Drug Administration has determined that it is necessary to remove from the market a distributed infant formula that is in violation of the laws and regulations administered by the Food and Drug Administration and that poses a risk to human health; or

(2) When a manufacturer has determined that it is necessary to remove from the market a distributed infant formula that:

- (i) Is no longer subject to the manufacturer's control;
 - (ii) Is in violation of the laws and regulations administered by the Food and Drug Administration and against which the agency could initiate legal or regulatory action; and
 - (iii) Does not present a human risk.
- (b) The Food and Drug Administration will monitor continually the recall action and will take appropriate actions to ensure that the violative infant formula is removed from the market.

§ 107.230 Elements of an infant formula recall.

A recalling firm shall conduct an infant formula recall with the following elements:

- (a) The recalling firm shall evaluate in writing the hazard to human health associated with the use of the infant formula. This health hazard evaluation shall include consideration of any disease, injury, or other adverse physiological effect that has been or that could be caused by the infant formula and of the seriousness, likelihood, and consequences of the diseases, injury, or other adverse physiological effect. The Food and Drug Administration will conduct its own health hazard evaluation and promptly notify the recalling firm of the results of that evaluation if the criteria for recall under § 107.200 have been met.
- (b) The recalling firm shall devise a written recall strategy suited to the individual circumstances of the particular recall. The recall strategy shall take into account the health hazard evaluation and specify the following: The extent of the recall; if necessary, the public warning to be given about any hazard presented by the infant formula; the disposition of the recalled infant formula; and the effectiveness checks that will be made to determine that the recall is carried out.
- (c) The recalling firm shall promptly notify each of its affected direct accounts about the recall. The format of a recall communication shall be distinctive, and the content and extent of a recall communication shall be commensurate with the hazard of the infant formula being recalled and the strategy developed for the recall. The

recall communication shall instruct consignees to report back quickly to the recalling firm about whether they are in possession of the recalled infant formula and shall include a means of doing so. The recalled communication shall also advise consignees how to return the recall infant formula to the manufacturer or otherwise dispose of it. The recalling firm shall send a followup recall communication to any consignee that does not respond to the initial recall communication.

(d) If the infant formula presents a risk to human health, the recalling firm shall request that each establishment, at which such infant formula is sold or available for sale, post at the point of purchase of such formula a notice of such recall at such establishment. The notice shall be provided by the recalling firm after approval of the notice by the Food and Drug Administration. The recalling firm shall also request that each retail establishment maintain such notice on display until such time as the Food and Drug Administration notifies the recalling firm that the agency considers the recall completed.

(e) The recalling firm shall furnish promptly to the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter, as they are available, copies of the health hazard evaluation, the recall strategy, and all recall communications (including, for a recall under § 107.200, the notice to be displayed at retail establishments) directed to consignees, distributors, retailers, and members of the public.

[54 FR 4008, Jan. 27, 1989, as amended at 66 FR 17358, Mar. 30, 2001; 69 FR 17291, Apr. 2, 2004]

§ 107.240 Notification requirements.

(a) *Notification of a violative infant formula.* A manufacturer shall promptly notify the Food and Drug Administration when the manufacturer has knowledge (as defined in section 412(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act)) that reasonably supports the conclusion that an infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer: